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ADVANTAGE™ SYSTEM
ADVANTAGE FIT™ SYSTEM

Transvaginal Mid-Urethral Sling

Kontakt den nærmeste Boston Scientific kundeserviceafdeling, hvis en dansk kopi af brugsanvisningerne ønskes. Spørg efter reservedel nr.: 90400965-02

Επικοινωνήστε με το γραφείο εξυπηρέτησης της Boston Scientific αν οι Οδηγίες Χρήσης απαιτείται να είναι στα Ελληνικά. Ζητήστε τον αριθμό ανταλλακτικού: 90400965-03

Kontakta Boston Scientific kundtjänst om ni behöver ett exemplar av en svensk bruksanvisning. Fråga efter del nummer: 90400965-05

Boston Scientific

EXHIBIT
F

DIRECTIONS FOR USE

℞ ONLY **Caution:** Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single patient use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness, or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

WARNING

This product is intended for use only by clinicians with adequate training and experience in the surgical treatment of stress urinary incontinence (SUI). The physician is advised to consult the medical literature regarding techniques, complications and hazards associated with the intended procedures.

DEVICE DESCRIPTION

This Product Contains No Detectable Latex

The Advantage™ System and the Advantage Fit™ System are sterile, single use systems, consisting of one delivery device and one mesh assembly. Each mesh assembly is comprised of a polypropylene knitted mesh protected by a disposable plastic sleeve. At the distal ends of the mesh assembly are two dilators designed to be placed over the needle end of the delivery device. The disposable delivery device consists of a handle with a curved needle, a sliding metal cannula with a blunt distal end and a pusher component. The delivery device is designed to facilitate the passage of the mesh assembly through bodily tissues for transvaginal placement.

INDICATIONS FOR USE

The mesh implant is intended as a suburethral sling for the treatment of stress urinary incontinence resulting from hypermobility and/or intrinsic sphincter deficiency.

CONTRAINDICATIONS

A mesh implant is contraindicated in the following patients:

- Pregnant patients, patients with the potential for future growth or patients that are considering future pregnancies.
- Any patients with soft tissue pathology into which the implant is to be placed.
- Patients with any pathology which would compromise implant placement.

- Patients with any pathology, such as blood supply limitations or infections that would compromise healing.

ENGLISH

GENERAL WARNING

The risks and benefits of performing a suburethral sling procedure in the following patients should be carefully considered:

- Women planning future pregnancies.
- Overweight women (weight parameters to be determined by the physician).
- Patients with blood coagulation disorder.
- Patients with a compromised immune system or any other condition that would compromise healing.
- Patients with renal insufficiency or upper urinary tract obstruction.
- Take special care in cases of bladder prolapse because of anatomical distortion. If the patient requires a cystocele repair, it should be done prior to the suburethral sling procedure.
- Vaginal and urinary tract infection should be treated prior to a suburethral sling implantation procedure.
- User should be familiar with surgical procedures and techniques involving nonabsorbable meshes.
- This product is intended for use only by clinicians with adequate training and experience in treatment of female stress urinary incontinence (SUI). The physician is advised to consult the medical literature regarding techniques, complications and hazards associated with the intended procedures.
- Good surgical practices should be followed for management of contamination or infected wounds.

PROCEDURAL WARNING

- User should note the importance of placing the mesh tension free under mid-urethra.

POST PROCEDURAL WARNING

- If subsequent infection occurs, follow appropriate medical intervention practices.
- The patient should be advised that future pregnancies may negate the effects of this procedure and the patient may again become incontinent.

PRECAUTIONS

- Standard surgical practices should be followed for the suburethral sling procedure as well as for the management of contaminated or infected wounds.
- The procedure should be performed with very careful attention to avoid laceration of any vessels, nerves, bladder and bowel.
- Retropubic bleeding can occur. Check carefully before releasing patient from the hospital.
- Cystoscopy must be performed to confirm bladder integrity.
- Do not remove the protective plastic sleeve covering mesh implant until proper position has been confirmed.
- Ensure the mesh is placed tension free under the mid-urethra.

- Use of this device should be done with the understanding that subsequent infection may require removal of the mesh.
- Patients should be counseled to refrain from heavy lifting, exercise, and intercourse for a minimum of four weeks after the procedure. Physician should determine when it is suitable for each patient to return to normal activities.
- Should dysuria, bleeding or other problems occur, the patient should be instructed to contact the physician immediately.
- Do not use any mechanical means of contact with the mesh (such as clips, staples, etc.) within the urethral support region of the mesh as mechanical damage to the mesh may occur.
- Avoid excessive tension on the mesh during handling.

ADVERSE EVENTS

The following complications have been reported due to the suburethral sling placement, but are not limited to:

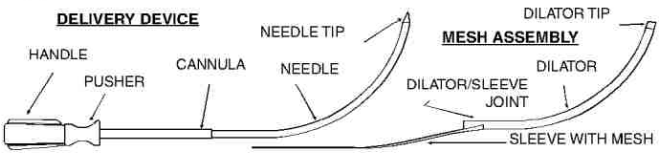
- As with all implants, local irritation at the wound site and/or foreign body response may occur.
- Tissue responses to the implant could include vaginal erosion/ extrusion, erosion through the urethra or other surrounding tissue, migration of the device from the desired location, fistula formulation and inflammation. The occurrence of these responses may require removal of the entire mesh.
- Like all foreign bodies, the mesh may potentiate an existing infection.
- Excess tension may cause temporary or permanent lower urinary tract obstruction and retention.
- Perforation or laceration of vessels, nerves, bladder, urethra or bowel may occur during placement and may require surgical intervention.
- Known risks of surgical procedures for the treatment of incontinence include pain, infection, erosion of the vaginal or urethral mucosa or bladder wall, device migration, complete failure of the procedure resulting in incontinence and mild to moderate incontinence due to incomplete support or overactive bladder.
- In addition to the above listed potential complications, allergic reaction, fistula, abscess, detrusor instability, pelvic and vaginal pain, dyspareunia, vaginal bleeding, vaginal discharge, dehiscence of vaginal incision, bruising/hematoma, edema and erythema at the wound site, have been reported due to suburethral sling procedures.

HOW SUPPLIED

The Advantage™ System and Advantage Fit™ System are sterile, single use systems consisting of one (1) delivery device and one (1) mesh assembly.

Store at a controlled room temperature. Do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that devices are used prior to the expiration date on the package label.

FIGURE 1



OPERATION INSTRUCTIONS

NOTE: Review image above for part description.

Operational Instructions Prior to Use

The Advantage™ System and Advantage Fit™ System are supplied sterile and are intended for single patient use only. Carefully examine the system to verify that neither the contents nor the sterilized package has been damaged in shipment. DO NOT USE if the sterile barrier on product is damaged. Immediately return damaged product to Boston Scientific.

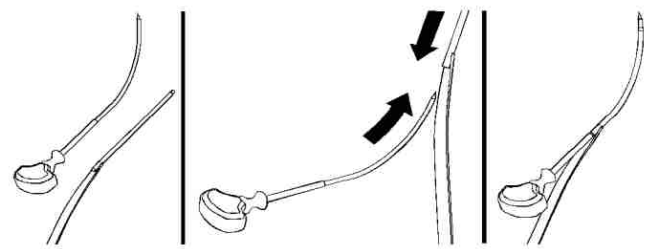
Prepare and drape the patient following standard surgical practice.

The design allows the operator a transvaginal route of placement.

> ***WARNING:*** Make sure that the bladder is empty prior to initiating the use of this product. Ensure that the bladder, urethra and other important landmarks are properly identified.

Prepare the System for Use

FIGURE 2



Preparing the System for Use (See Figure 2)

1. Orient the Delivery Device handle so that the needle end is positioned away from the user and the needle tip is positioned upward.
2. Load the proximal end of the dilator tube by holding the dilator/sleeve joint and placing it over the distal end of the needle.
3. Slide the dilator tube over the needle until the dilator's proximal end abuts the distal end of the dilator pusher.

STEPS FOR USE

1. After preparation of the lower abdominal and vaginal operative sites, create two small transverse abdominal incisions approximately 0.5 cm to 1 cm on each side of the midline just above the symphysis.
2. Incise the anterior vaginal wall and dissect bilaterally in standard fashion.
3. Resting the tip of the needle on the palmar surface of the non-dominant index finger, gently introduce the delivery device anterolaterally into the paraurethral space.

WARNING: Make sure the delivery device needle and mesh assembly pass sufficiently lateral to the urethra and bladder so that neither is injured.

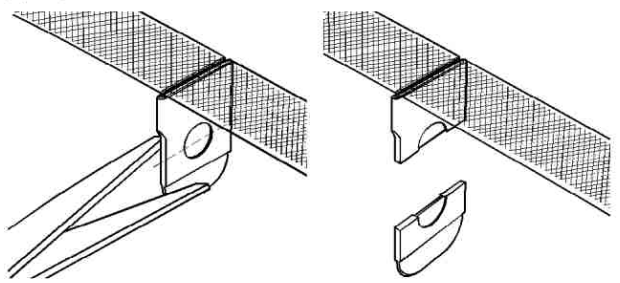
4. After perforating the endopelvic fascia, use your fingertip, and guide the distal end of the needle superiorly along the posterior surface of the pubic bone. The curved part of the needle should rest in the operator's non-dominant hand during advancement of the device.
5. Carefully pass the needle through the space of Retzius and perforate the rectus sheath and muscle. Guide the device into the ipsilateral abdominal incision until the needle tip is exposed through the incision.

WARNING: If excessive resistance is encountered during advancement/withdrawal, stop and determine remedial action prior to proceeding.

6. When the needle tip/dilator tube assembly extends extra-abdominally, advance the dilator pusher on the handle forward toward the needle tip end of the Delivery Device. This will cause the dilator tube to advance beyond the tip of the needle.
7. Grasp the dilator by placing a clamp or hemostat on the free end of the dilator end to temporarily secure it extra-abdominally.
8. While holding the dilator in position, withdraw the needle from inside the dilator and out of the vagina. If the dilator should retract back into the abdomen, advance the needle until the proximal end of the dilator abuts the distal end of the cannula and redeploy the Dilator/Mesh Assembly until the needle tip/dilator tube assembly extends extra-abdominally.
9. Repeat steps 1-8 on the contra lateral side.
10. With both dilator tubes in place, cystoscopy should be performed to confirm bladder integrity. If the blue dilator is seen in the bladder, remove the Dilator/Mesh Assembly. Visually inspect the Dilator/Mesh Assembly for integrity. If the Dilator/Mesh Assembly is intact, reload the Delivery Device and redeploy the Dilator/Mesh Assembly. The bladder must be emptied after cystoscopy.
11. Once desired placement is achieved, prepare to remove the protective sleeve from the mesh. See Section **Tension Mesh/Sleeve Removal**.

Tension Mesh/Sleeve Removal

FIGURE 3



Tension Mesh/Sleeve Removal

1. Adjust the mesh by pulling upwards on the dilators so that urine leakage is limited to no more than one or two drops. During this

process keep the vaginal incision closed by means of a gentle grip with small forceps.

2. When the appropriate placement is attained, grasp the blue centering tab and cut the tab through the center of the punch hole (See Figure 3) ensuring that both halves of the blue tab are completely removed from the vaginal canal.
3. Pull upwards on the dilators to remove the sleeve out of the body.
4. Verify the tension of the Mesh and adjust mesh as necessary.
5. Once the desired tension has been achieved, gently push downward on the abdomen, cut the distal ends of the mesh and confirm that those ends retract into the incision.
6. Close the incision in the usual manner.

POTENTIAL COMPLICATIONS

The following complications have been reported as consequences that may occur in a suburethral sling procedure:

- Allergic reaction
- Fistula
- Abscess
- Irritative voiding symptoms including urgency and urge incontinence
- Detrusor instability
- Infection
- Pelvic, vaginal pain
- Urinary retention
- Dysparenia
- Vaginal bleeding
- Vaginal discharge
- Erosion of the vaginal or urethral mucosa or bladder wall
- Dehiscence of vaginal incision
- Edema at the wound site
- Erythema at the wound site
- Bruising / Hematoma
- Recurrent Stress Urinary Incontinence

WARRANTY

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. BSC's obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage, or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**